



Office of the Gene Technology Regulator

**REPORT  
ON  
AUDIT OF  
UNIVERSITY OF WESTERN AUSTRALIA**

**Conduct of field trials  
in accordance with  
GMAC recommendations**



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## A. BACKGROUND

### 1. The trials

The planned release proposals PR74, PR75 and PR76 were submitted to the Genetic Manipulation Advisory Committee (GMAC) for assessment in 1997. The proposals related to trials of transgenic lupins, to be conducted in 1997 and 1998.

The field trials were run by the Centre for Legumes in Mediterranean Agriculture (CLIMA), a Cooperative Research Centre (CRC) between the University of Western Australia (UWA), Agriculture Western Australia (AGWEST) and others. The CRC was subsequently discontinued, but CLIMA was subsumed into the Faculty of Agriculture of UWA, as a research centre.

GMAC recommended various conditions for these trials, which evolved over time. The conditions are set out in Attachment 1.

#### *PR74*

The aim of PR74 was to assess the field performance of lupins (*L. angustifolius*) modified for resistance to the herbicide Basta®.

The post-trial monitoring conditions for PR74 state that there was to be a two-year break before lupins were to be grown again on the trials sites. The sites were to be monitored for volunteer lupin plants during this period and any such plants, if found, were to be removed and destroyed before flowering.

PR74 trials were conducted at a total of 23 sites in 1997 and 1998.

#### *PR75 and PR76*

The PR75 trial was to assess the performance of *L. luteus* and the PR76 trial to assess the performance of *L. angustifolius*. Lupins in both trials had modified for both herbicide and virus (Bean Yellow Mosaic Virus) resistance.

GMAC's advice for post-trial monitoring in relation to PR75 and PR76 was that no *L. luteus* was to be grown on the sites for at least four years after the trials, and that any volunteer lupins that grew on the sites during these four seasons were to be removed and destroyed before flowering.

However, in the end, only two preliminary field trials were conducted (in 1998) under PR75, and no PR76 trials were conducted. GMAC agreed to the amendment of post-trial monitoring requirements at one of the PR75 sites to 2 years (as opposed to 4).

Screen house testing of PR75 and PR76 was undertaken in 1997.

## 2. Previous investigations

On 28 September 2000, UWA's Institutional Biosafety Committee (IBC) informed the Interim Office of the Gene Technology Regulator (IOGTR) that viable lupins which had reached or passed flowering stage had recently been discovered at past trial sites of genetically modified (GM) lupins. The potential breach involved two PR74 trials conducted in 1998, one at Mingenew and the other at Quairading (both in Western Australia).

As stated above, GMAC recommendations require post trial monitoring of these sites for two years, during which time volunteer lupins are to be destroyed before flowering.

Details of the alleged breach site at Mingenew revealed that volunteer lupins were found amongst canola that had been sown over the past trial site. Surrounding the site were lupin agronomy trials, with a buffer crop of lupin sown later in the season. The agronomy trials were non-transgenic. The new lupin trials, while reported as not being present on the past site, posed a concern (albeit a very minor one) because of possible cross-pollination from volunteer transgenic lupins on the past site that had been allowed to flower.

Details of the Quairading site also revealed that volunteer lupins were found amongst canola that had been sown over the past trial site.

UWA listed a number of risk management actions that they proposed to undertake for the two sites. Details are as follows:

For the Mingenew site:

- The volunteer lupins were to be hand weeded on a continuous basis as new volunteers are discovered.
- The lupin agronomy trial buffer was to be slashed out in case pollination had occurred.
- Mature lupins from the agronomy trial were to be harvested and destroyed by deep burial in case pollination had occurred.

For the Quairading site:

- The volunteer lupins were to be hand weeded on a continuous basis as new volunteers are discovered.

CLIMA also listed some future management actions to be undertaken at both the Mingenew and Quairading sites, including:

- Making the property manager/farmer fully aware of the monitoring requirements.
- Sites to be planted to cereal or pasture.
- That the sites be two years clear of volunteer lupins before monitoring ceases.
- That the sites be inspected in pre-season (March/April depending on the location), then in July/August 2001 before flowering occurs.
- That the sites be re-inspected in September/October 2001 for additional late emergence of volunteers.

The information relating to the breaches was provided to GMAC, who discussed the issue and agreed with the proposed management actions being undertaken by CLIMA. GMAC considered that the breaches presented negligible risks to human health and to the

environment. GMAC had previously indicated in its advice for PR74 that lupins show only a low level of cross-pollination within the species, and that hybridisation with other species does not occur.

In November 2000, an IOGTR staff member inspected the site at Quairading. The inspection discovered a number of volunteer lupin plants still on the site that had passed the flowering stage and had begun seed set. The lupin plants were very small in size (2-10 cm) and would have been difficult to detect amongst the canola crop planted during October/November. The lupin plants found during the site inspection were removed at that time and destroyed. The Mingenew site was reported to have been cultivated to destroy all viable plants.

### **3. Reason for audit**

The investigation of the breaches at the Quairading and Mingenew sites highlighted an apparent need to clarify the roles and responsibilities for ongoing management of the PR74 and PR75 trials since the discontinuation of CLIMA as a CRC. In addition, the investigation suggested a possible weakness in the operation of post-trial monitoring at all trial sites conducted under PR74 and PR75. The IOGTR therefore decided to conduct an audit to satisfy itself that the remaining trial sites were being appropriately managed.

## **B. ABOUT THE AUDIT AND ITS PROCESSES**

On 5 February 2001 the IOGTR notified UWA of its intention to conduct an audit. The Audit Plan is at Attachment 2.

The objectives of the audit were:

- To identify whether there are any deficiencies in the processes employed to control sites which were the subject of field trials under PR74, PR75 and PR76, and that this control is in accordance with the post-trial recommendations made by the Genetic Manipulation Advisory Committee (GMAC).
- To identify and consider options for action in relation to any deficiencies identified in the above process.

### **1. Context of audit**

The trials in question were conducted under the administrative system for the oversight of dealings with genetically modified organisms (GMOs) in Australia, and prior to the IOGTR implementing its compliance monitoring protocol in October 2000. The audit was therefore conducted in the absence of regulatory underpinning, and organisations dealing with GMOs under this system chose to voluntarily comply with GMAC recommendations.

As such, the IOGTR and GMAC did not have any legislative basis to access documents or information necessary for the conduct of this audit and relied on the cooperation of the UWA, and other parties involved in the management of the trials, to provide such information.

With the coming into force of the *Gene Technology Act 2000* on 21 June 2001, failure to manage field trial sites subject to licences under this Act in accordance with conditions prescribed by the Gene Technology Regulator (Regulator) can now result in sanctions being applied under the Act, including criminal prosecution.

## **2. Provision of information**

UWA was asked to provide information to assist the audit. The information requested included:

- i) Any monitoring reports.
- ii) A description of the procedures that were in place for monitoring of field trials.
- iii) Minutes of any meetings that were relevant to the post trial monitoring and supervision of field trials.
- iv) Other documentation and correspondence that UWA believed to be relevant to the audit.

UWA also provided detailed information in relation to the conduct of the field trials under PR-74, PR-75 and PR-76 and explanations as to why they believed there were inadequacies in the management practices undertaken.

## **3. Request for additional information**

On 28 February 2001, the audit committee wrote to UWA seeking additional information. The additional information sought included further information and clarification on the management of the field trials undertaken by UWA, and information concerning the management of particular trial sites.

On 19 April 2001, the UWA provided some of the additional information that was requested, with further information being provided on 11 May 2001. UWA hired a consultant to research all issues thoroughly in order to provide the IOGTR with as detailed information as possible. The final piece of information requested by the IOGTR on 28 February 2001 was provided by UWA on 24 May 2001.

## **C. FINDINGS**

### **1. Summary**

The audit committee found that the management practices used in the GM trials under PR-74 and PR-75 were deficient in a number of areas. No concerns to human health or to the environment were identified.

In particular, communication between and within the UWA and AGWEST caused confusion over which organisation had responsibilities for the supervision of the trials, and left the researchers to undertake most of the trial management.

Inadequate training and record keeping in UWA and AGWEST in relation to the trials also contributed to difficulties in maintaining appropriate supervision of the trial sites. Whilst

information was kept in relation to most sites, the information was not readily available at a central point such as the project supervisor, or the IBC.

These communication and record-keeping deficiencies resulted in:

- Difficulties in being able to accurately identify the location of a number of trial sites.
- Certain trial sites not being monitored at all or being inadequately monitored.
- Inappropriate crops being planted on the trial site within the two-year monitoring period.

Consideration of UWA records identified potential concerns with a further four trials (in addition to the two suspect trials found during the original breach investigation), bringing the number of trials with potential problems to a total of six out of the twenty five trials. However, the audit committee believes, based on GMAC advice that the original breaches presented negligible risk and as a result of the preventative steps implemented by UWA, that the risks to human health and to the environment resulting from these further concerns are negligible.

## **2. Communication**

The audit committee identified a number of problems with communication between the separate organisations within the CRC.

A good example of this communication breakdown was provided to the audit committee as the audit progressed. GMAC had sought to clarify the division of responsibilities in regards to PR75 in mid 1998. On 28 July 1998 the Secretary of the AGWEST IBC responded to this request and stated that the AGWEST IBC understood that it only had responsibility for certain glasshouse trials of PR74 and PR75. GMAC's assumption was that this understanding was on the basis of agreement with UWA.

However, it would appear that UWA was not made aware of this correspondence. This led to confusion over the management of the PR74 and PR75 trial sites, with the monitoring and overseeing of activities becoming the responsibility of the researchers.

## **3. Record keeping and training of personnel**

The confusion over responsibilities for the supervision of the trial sites manifested itself through inadequate management of a significant number of trial sites. Some trial sites were not monitored properly, with one not being monitored at all.

Because several of the PR74 trial sites were located on AGWEST research stations, the primary researcher (CLIMA's then Director) nominated AGWEST personnel to manage some of the PR74 trial sites in 1997 and 1998. This primary researcher was under the impression that these personnel would report to AGWEST's IBC (despite this IBC's belief that it was not supervising these trials).

From information that was provided to the audit committee by UWA, the committee concluded that on a number of occasions technical officers responsible for monitoring the trial sites were therefore not given sufficient advice or preparation on how to monitor the trial sites adequately. The audit committee found that not all technical officers received written instructions or copies of the GMAC advice relating to the trials, nor were these

officers informed of the expectation that they would provide written documentation of their activities. As such, they were not fully aware of what the monitoring requirements were or what events would constitute a breach of the GMAC guidelines.

As such, most of the sites which were found to have potential management deficiencies were located at these research stations (refer below).

#### **4. Management deficiencies at specific trial sites**

The audit committee identified potential management deficiencies at a further five sites in addition to the two previously investigated.

The trial sites at these locations were found to have a number of management problems including:

- inadequate or non-existent monitoring,
- volunteers that had reached maturity,
- poor recording of the site location, or
- being planted with lupin crops before the two year monitoring period had expired.

An assessment of these deficiencies is set out below under Part 6 “Risks to the environment and to public health and safety”.

#### **5. Further sites**

**UWA also identified a further site (Northam) which it would prefer to continue to monitor until 2 years clear of lupins, because of possible non-wetting soil issues associated with the site (leading to a possible persistence of volunteers). However, the site had been correctly managed during the post-trial monitoring period recommended by GMAC**

**The audit committee believes that another site (Gnowangerup) was managed in accordance with GMAC recommendations, following confirmation that the locational details for the site were accurate.**

#### **6. Risks to the environment and to public health and safety**

##### *Risks to the environment*

Risks to the environment could potentially result where volunteer GM lupins reached flowering stage, resulting in the potential for cross-pollination with sexually compatible weedy species. The audit committee identified the potential appearance of flowering volunteers at a total of five different trial sites (Wongan-Ballidu, Mullewa, Mingenew, Quairading, and Lake Grace).

Following previous advice from GMAC that lupins show only a low level of cross-pollination within the species, and that hybridisation with other species does not occur, the audit committee believes that these identified management deficiencies presented negligible risks to the environment.

In addition, genetically modified lupins that reach seeding stage may pose a concern to the environment where they are transported offsite, or where there is continual replenishment of the seed bank at a site without removal of volunteers. At sites where lupins were grown over trial sites, the later lupin crops were harvested and the seed destroyed completely at one site (Mullewa), and either destroyed or reused on location at a second site (Lake Grace), thereby reducing the risks. In the event that volunteer lupins have been mixed with non-transgenic lupins and reused, the risks to the environment are considered negligible, as lupins do not hybridise with other species.

At a third site, also in Mullewa, where non-transgenic lupins were grown over a trial site before post-trial monitoring had been completed, the risks to the environment were also considered by GMAC to be negligible, as the actual GM trial in 1997 was not allowed to set seed in the year of sowing, being mowed just after flowering. A herbicide application was also applied to control lupins prior to the 1998 planting with barley, which would have destroyed any volunteers in the following year.

### *Risks to human health*

Risks to human health may result from the genetically modified trait entering the food chain. This may occur as a result of flowering volunteers cross-pollinating with food crops. However, given GMAC's advice that lupins do not hybridise with other species, the audit committee believes that risks resulting from such cross-pollination are negligible.

The genetically modified trait may also enter the food chain through the growing and harvesting of a non-transgenic crop on the trial site, where the site contains volunteers that have reached the seeding stage. However, the audit committee identified that at two sites where this was found to have occurred (Mullewa and Lake Grace), the harvested lupin crops were either destroyed, or did not enter the **human** food chain. At a third site, also in Mullewa, the risks to human health were also considered by GMAC to be negligible, as the actual GM trial in 1997 was not allowed to set seed in the year of sowing, being mowed just after flowering. A herbicide application was also applied to control lupins prior to the 1998 planting with barley, which would have destroyed any volunteers in the following year.

As such, the audit committee believes that the risks to human health as a result of identified management deficiencies with UWA's trials of genetically modified lupins are negligible.

## **D. RECOMMENDATIONS**

### **1. Post Trial monitoring**

1. The audit committee recommends the continuation of the preventative post-trial monitoring actions that UWA have implemented at the trial site locations where potential management deficiencies were identified, and **also at the Northam site (where potential volunteer problems post-trial have been identified).**

These practices will ensure monitoring of these sites will be conducted under terms similar to the original GMAC conditions, until the sites are two years clear of

volunteer lupins. Other lupin crops will also not be planted on the sites until the monitoring has ceased. The management practices developed by UWA include monitoring of the sites three times throughout the year, and the accurate recording of the site locations. Field officers are now fully aware of the site location details and of these monitoring requirements.

**The site at Gnowangerup does not require further monitoring.**

2. The Office of the Gene Technology Regulator should investigate mechanisms to enforce these activities under the *Gene Technology Act 2000*.

The audit committee notes that UWA was pro-active in undertaking a number of important steps to rectify the issues identified with the trial sites.

**2. Management of GM trial sites.**

In regards to improving the management of future GM trials, and of the post-trial monitoring of current sites, the audit committee recommends that UWA:

1. develops a Quality Assurance system and/or Standard Operating Procedures for the management of GM crop trials,
2. provides appropriate training for all staff involved in GM crop trials,
3. appropriately documents the location of all trial sites using GPS coordinates,
4. record details of all monitoring activities, including the personnel undertaking these activities and any changes in personnel,
5. reports any identified breaches of field trial conditions as soon as possible to the OGTR, and
6. develops a central recording system to ensure information relating to the GM crop trials is easily accessible by appropriate people, including the OGTR.
7. ensures that the UWA IBC does not approve any future GM research proposals unless the above recommendations are incorporated into the research proposal.

**3. OGTR auditing**

1. The audit committee recommends that OGTR monitoring staff undertake an inspection of the trial sites, and of UWA's record-keeping procedures, by the end of 2001 to ensure that the recommended management practices have been implemented and are being maintained.

**E. REFERENCES/DOCUMENTS CONSIDERED BY AUDIT COMMITTEE**

1. UWA correspondence (28 September 2000) to GMAC Secretariat concerning volunteer lupins present in past field trial sites associated with PR -74, PR-75 and PR-76 and attached report written by the project supervisor dated 20 September 2000.
2. Notes of a phone conversation between IOGTR and the project supervisor on 18 October 2000 on regrowth of lupins.
3. CLIMA Correspondence (11 May 1998) providing information on the sites to be used for 1998 transgenic lupin field trials under PR-74 and PR-75.
4. GMAC document: Minutes of Planned Release Subcommittee meeting (30 May 1997) considering proposals for PR-74, PR75 and PR-76.
5. Notes of phone conversation between IOGTR and the project supervisor on 17 December 2000 detailing that all sites of concern fell within PR-74.
6. CLIMA Correspondence (7 January 1998) to GMAC Secretariat detailing changes to proposal for PR-74.
7. UWA correspondence to IOGTR (22 December 2000) providing details of material collected from Quairading and Mingenew.
8. IOGTR Breach Inspection Report (21 November 2000) on monitoring conducted on a site under PR-74 at Quairading.
9. UWA correspondence (2 February 2001) to IOGTR outlining circumstances leading to the incidents, changes to management practices to control the situation and site details.
10. UWA correspondence (9 February 2001) to IOGTR providing information on post trial monitoring information and trial site details. An AGWEST IBC briefing to CEO of AGWEST on the issue was also attached.
11. UWA correspondence (12 April 2001) to IOGTR detailing actions taken in regard to monitoring and management of the trial sites and listing these activities
12. AGWEST correspondence (28 July 1998) to GMAC Secretariat outlining AGWEST's understanding of responsibilities for supervision of PR-74 and PR-75.
13. Document provided to IOGTR by the consultant on behalf of UWA (Received 24 April 2001): Answers to GTR audit queries contained in TGA letter to the project supervisor dated 28/02/01.
14. Document provided to IOGTR by UWA – the project supervisor (Received 11 May 2001): Audit Answers Part B.
15. Correspondence from UWA to IOGTR (24 May 2001) detailing the fate of lupins harvest in 1999 and delivered in bulk to the Mullewa bin.

16. Correspondence from UWA to IOGTR (4 May 2001) clarifying planting of lupins under PR -74 trial sites and providing further monitoring tables.

## **Attachment One**

### **GMAC advices for Planned Release Proposals PR-74, PR-75 and PR-76**

<http://www.ogtr.gov.au/gmorecord/pdfdir/pr74lupins.pdf>

<http://www.ogtr.gov.au/gmorecord/pdfdir/pr75lupins.pdf>

<http://www.ogtr.gov.au/voluntary/pdfgmac/pr76.pdf>

## **Attachment Two**

### **Audit Plan**

<http://www.ogtr.gov.au/publications/bulletin9.htm>

